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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,398	06/24/2003	Xiaoyi Min	A03P1046	4855

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/603,398	MIN ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-21* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12072005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The amendments to the specification are acknowledged and accepted. The objections are withdrawn.

Double Patenting

2. The provisional double-patenting rejections, based on the amendment of Serial No. 10/603,429, are withdrawn.

Response to Arguments

3. Applicant's arguments filed 12/7/2005 have been fully considered but they are not persuasive. In regards to the rejection of independent claims 1 and 21, Applicant argued that Stradler et al. (US 6,381,493 hereinafter "Stradler") does not disclose utilizing a maximum slope to detect ischemia, but uses a "ST change" parameter, which is an indication of an ST shift in relation to a baseline value. Examiner concedes that Stradler does utilize this "ST change" parameter to detect ischemia, but Stradler also discloses that their method utilizes a maximum slope as well (col. 19, line 58; col. 21, line 64; and col. 22, line 24). Please note that the excerpt at column 22, line 24 discloses that the parameters (i.e. slopes) are compared to ranges, thus determining a "maximum slope". Please also refer to Verrier et al. (US 5,148,812 hereinafter "Verrier"), column 1, line 54, for evidence that the ST segment is part of the T-wave.

Additionally, in its "broadest reasonable interpretation", Examiner maintains the assertion that Stradler's "ST change" parameter can be interpreted as "an energy value" because it is a measure of potential energy (voltage).

4. In regards to claims 11 and 13, Applicant argued that the normalization disclosed by Stradler does not involve T-waves, does not involve a running average, does not calculate a difference between the current value and a sinus or paced running average, does not determine whether the difference exceeds a predetermined threshold, and the protocol disclosed by Stradler in column 23 is for noise detection and not ischemia detection. However, as elaborated above, the "ST change" parameter is a "T-wave energy value". Column 6, line 45 was cited merely to illustrate that the ST change parameter is normalized to the R-wave. This ST change parameter is one of the seven parameters that are compared to the running means and thresholds disclosed in column 23, line 11. As disclosed in column 29, line 21, there are separate means and thresholds for sinus and paced beats. In response to the argument that the steps described by Stradler are for noise detection and not ischemia detection, in its broadest reasonable interpretation everything that Stadler discloses is ultimately for detecting ischemia. Therefore, ischemia detection comprises any and all disclosed steps, whether for filtering, noise detection, or any other sub-process.

5. In regards to claim 17, Applicant argued that using a single sample for the T-wave "window" is confusing and contrary to Verrier's teaching that the T-wave is partitioned into "B" time divisions because the T-wave would not be partitioned, or in the alternative, if each of several samples is considered, the energy would not be for an

entire T-wave. In light of column 6, line 42-51, Applicant's argument of contrary teachings is irrelevant. Because there is no combination of references or teachings, but only an explicit disclosure of all claimed elements, no consideration of operability of the combination needs to be made. Verrier clearly states that the energy of the entire T-wave is computed when "B" is a single digital sample.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 5, 7, 10-16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al. (6,381,493).

8. In regards to claim 1, Stadler et al. disclose a method comprising detecting ventricular repolarization events, determines energy values, and detects ischemia based on the energy values (col. 4, line 60). Examiner is interpreting the energy values to be potential energy (voltage) measured by the electrodes. Furthermore, the maximum slope is used to determine the ischemic event (col. 23, line 28).

9. In regards to claims 3 and 12, ectopic beats are discarded (col. 23, line 50). Examiner is interpreting arrhythmia as comprising ectopic beats because the beats occur at abnormal times.

10. In regards to claim 5, the repolarization peaks are used to define repolarization windows (col. 32, line 58).

11. In regards to claim 7, the depolarization peaks are used to define repolarization windows (col. 19, line 65).

12. In regards to claim 10, detecting ischemia is based on whether the ventricular repolarization is a paced or sinus beat (col. 29, line 21).

13. In regards to claim 11, the sinus repolarization event is normalized with respect to the depolarization event (col. 6, line 45), a sinus event running average is maintained, the average compared to the current beat, and the difference is compared to a sinus beat threshold (col. 23, line 10).

14. In regards to claim 13, the paced repolarization event is normalized with respect to the depolarization event (col. 6, line 45), a paced event running average is maintained, the average compared to the current beat, and the difference is compared to a paced beat threshold (col. 29, line 21).

15. In regards to claim 14, fused beats will inherently be ignored because the R-R parameter will be outside of the "expected range" (col. 23, line 28).

16. In regards to claims 15 and 21, a warning signal is generated to indicate the onset of ischemia (col. 8, line 55).

17. In regards to claim 16, the warning signal is an internal signal applied directly to patient tissue and has a stimulation frequency different than any other warning signal (col. 12, line 51). Please note that the stimulation frequency is inherently different than

other alarms because it is the only alarm ("audible alarm **or** a stimulation of the patient's skin").

18. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Verrier et al. (5,148,812). Verrier et al. disclose a T-wave detection subsystem (308), T-wave energy integration subsystem (312), and ischemia detection subsystem (col. 6, line 60). Please note that "B" in step 310 can be a single sample (col. 6, line 42), making the energy integration a "total energy" integration.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. Stadler et al. disclose the claimed invention but does not disclose expressly a repolarization window with the limits of 150ms before and 150ms after the repolarization peak or 80ms to 480ms after the depolarization peak. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the limits of the repolarization window as taught by Stadler et al. by providing a repolarization window with the limits of 150ms before and 150ms after the repolarization peak or 80ms to 480ms after the depolarization peak because applicant has not disclosed that these specific limits provide an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, the durations of the windows are not even consistent between the two methods. One of ordinary skill in the art would have expected Applicant's invention to perform equally well with the T-wave window as taught by Stadler et al. because the window in his invention samples the entire ST segment. Therefore, it would have been an obvious matter of design choice to modify Stadler et al.'s invention by providing a repolarization window with the limits of 150ms before and 150ms after the repolarization peak or 80ms to 480ms after the depolarization peak to obtain the invention as specified in the claims.

22. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Goldin (2002/0151807). Stadler et al. disclose the essential features of the claimed invention except for sensing bipolar signals in the atrium, sensing unipolar signals elsewhere, and subtracting the bipolar signal from the unipolar signal to sense substantially only ventricular events (par. 0045). Goldin teaches of a method

comprising sensing near-field and far-field signals and subtracting the far-field signals to reduce far-field noise. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Stadler et al.'s invention by sensing bipolar signals in the atrium, sensing unipolar signals elsewhere, and subtracting the bipolar signal from the unipolar signal to signals to reduce far-field noise and sense substantially only ventricular events.

23. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stadler et al. in view of Verrier et al. Stadler et al. disclose the essential features of the claimed invention except for summing individual samples of the digitized T-wave signal to compute total energy. Verrier et al. teach of a method comprising summing individual samples of the digitized T-wave signal to compute total energy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Stadler et al.'s invention by summing individual samples of the digitized T-wave signal to compute total energy.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. in view of Stadler et al. Verrier et al. disclose the essential features of the claimed invention except for using T-wave slope; an ischemia warning system; and separate units to analyze paced beats and sinus beats. Stadler et al. teach of using the slope of T-waves to detect ischemia, an ischemia warning system to indicate that a patient should seek medical care, and separate units to analyze paced beats and sinus beats to reduce false-positive indications of ischemia due to the wide QRS complex and steep ST segment of paced beats (col. 29, line 12). Therefore, it would have been obvious to

one having ordinary skill in the art at the time the invention was made to modify Verrier et al.'s invention by using the slope of T-waves to detect ischemia, an ischemia warning system to indicate that a patient should seek medical care, and separate units to analyze paced beats and sinus beats to reduce false-positive indications of ischemia.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/3/6

MWK